APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 2, 1995 Decided April 25, 1995

No. 93-5404

THE AMERICAN LEGION,

Appellant

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; WILLIAM L. ROPER, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL; VERNON N. HOUK, DIRECTOR, CENTER FOR ENVIRONMENTAL HEALTH AND INJURY CONTROL CENTER; UNITED STATES OF AMERICA,

Appellees

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and Consolidated Case No. 94-5013

VIETNAM VETERANS OF AMERICA; HAROLD A. BUTLER; CAROL RIDOLFI-DELANEY; MAREL J. MACKI; BEVERLY NEHMER,

Appellants

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES;

WILLIAM L. ROPER, M.D., DIRECTOR,
CENTERS FOR DISEASE CONTROL;
VERNON N. HOUK, DIRECTOR, CENTER FOR
ENVIRONMENTAL HEALTH AND
INJURY CONTROL CENTER;
UNITED STATES OF AMERICA,
Appellees

Appeals from the United States District Court
for the District of Columbia
(90cv1808)

Before: EDWARDS, *Chief Judge*; RANDOLPH and ROGERS, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The American Legion and others appeal from the grant of summary judgment rejecting their challenge to the decision of the Secretary of Veterans Affairs to abandon a congressionally mandated epidemiological study of the effects of exposure to dioxin, a by-product of Agent Orange and other herbicides, on Vietnam veterans.[1] The district court ruled that the Secretary had acted within his discretion in abandoning the Agent Orange Study, which the Secretary had commissioned the Centers for Disease Control to design and conduct, after determining that sampling problems made it unlikely that the investigation would yield scien-

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[1] In 1988, Congress redesignated the Veterans Administration as the Department of Veterans Affairs and named the Secretary of Veterans Affairs (previously, the Administrator of Veterans' Affairs) to head the department. Department of Veterans Affairs Act, Pub. L. No. 100-527, 102 Stat. 2635 (1988). We use the current title "Secretary" in this opinion whenever the statute or record refers to the Administrator of Veterans' Affairs.

tifically valid results. *American Legion v. Derwinski*, 827 F. Supp. 805, 812-14 (D.D.C. 1993). Appellants contend that the Secretary erroneously relied on a repealed standard as the basis for abandoning the study and violated the statute by halting the study before submitting a mandated report of health results to Congress; alternatively, they challenge as arbitrary and capricious the Secretary's conclusion that a scientifically valid study was impossible. Finding these contentions unpersuasive, we affirm.

I.

As background to appellants' contentions, we first outline the statute and the Secretary's efforts to implement the statutory directive for an epidemiological study on the effects of exposure to dioxins during the Vietnam conflict.

A. The Statute. In enacting the Veterans' Health Programs Extension and Improvement Act of 1979, Pub. L. No. 96-151, 93 Stat. 1092 (codified as amended at 38 U.S.C. § 219 note (1988)), *reprinted as amended in* 38 U.S.C.A. § 527 note (1991) (the "1979 Act"), Congress sought to determine by means of an epidemiological study the health effects of exposure to Agent Orange and other herbicides on Vietnam veterans.[2] *Id.* § 307; *see also* S. REP. No. 260, 96th Cong., 1st Sess. 36-40 (1979) ("1979 S. REP."), *reprinted in relevant part in* 1979 U.S.C.C.A.N. 1894, 1922-1926. These herbicides, which the United States military used during the Vietnam conflict, contain varying amounts of dioxins—also

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[2] Epidemiology is "a branch of science and medicine [that] uses studies to 'observe the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations.'" *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945 (3d Cir. 1990) (quoting Black & Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 Fordham L. Rev. 732, 755 (1984)); *see also* Affidavit of Dr. Zena A. Stein, proffered by appellants, at 2.

referred to as TCDD [3]—which studies have suggested can cause harmful health effects in laboratory animals and consequently led to concern about similar effects in humans.[4] Congress sought to determine whether Vietnam veterans had suffered such adverse health effects as a result of their military service and, if so, to compensate them for their injuries. *See* 1979 S. REP. at 38-40.

The 1979 Act directed the Secretary to conduct an epidemiological study pursuant to a protocol approved by the director of the congressional Office of Technology Assessment ("OTA"). 1979 Act § 307(a)(2)(A)(i). The statute also required the director of OTA to oversee the conduct of the study and report its oversight activities to the appropriate congressional committees. *Id.* § 307 (a)(2). Further, as part of the effort to ensure that the study was "sientifically valid and . . . conducted with efficiency and objectivity," the 1979 Act directed the President to coordinate the Secretary's study with any other Federal governmental studies on the effects of dioxins. *Id.* § 307(c). The 1979 Act expressly required, however, that the Secretary continue the study only "for as long after the submission of [his first] report [to Congress on 'the results thus far obtained under the study'] . . . as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." *Id.* § 307(a)(3), (b)(2).

The 1979 Act initially called for an epidemiological study of veterans who "were exposed to" dioxins during the Vietnam conflict. *Id.* § 307(a)(1) (amended 1981). From the outset, a major obstacle to completion of the study was the identification of veterans, other than "Ranch Hands" who did the actual spraying, who had

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[3] TCDD stands for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin, a by-product created during the manufacture of certain herbicides.

[4] *See* 1979 S. REP. at 37-39; Health Study Protocol at 4-5.

been exposed to Agent Orange during their service in Vietnam. S. REP. No. 89, 97th Cong., 1st Sess. 25 (1981) ("1981 S. REP."). To adress this problem, Congress amended the statute in 1981 to require a study of veterans' health effects that "may result" from exposure to dioxins. Veterans' Health Care, Training, and Small Business Loan Act of 1981, Pub. L. 97-72 § 401(a)(1), 95 Stat. 1061 (1981) (codified at 38 U.S.C. § 219 note (1988)), *reprinted in* 38 U.S.C.A. § 527 note ("1981 Amendments"). The 1981 Amendments also expanded the scope of the study to examine health effects that may have resulted from other factors in the overall Vietnam experience, "including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions." *Id.* According to the Senate Report, the amendments were intended to "allow the Secretary to begin the study of the health status of these veterans by identifying a population of veterans who served in Vietnam, without first having to determine whether each was, without question, exposed to Agent Orange in Vietnam." 1981 S. REP. at 26.

B. The Health Study Protocol and Pilot Study. Following enactment of the 1981 Amendments, the Secretary entered into a contract with the Centers for Disease Control ("the Center") to design a protocol for the epidemiological investigation. The Center's Health Study Protocol, completed in November 1983, proposed three studies to evaluate the health of Vietnam veterans, one of which was the "Agent Orange" Study, designed to examine the effects of exposure to Agent Orange and other herbicides on veterans' health. *See* United States Department of Health and Human Services, Public Health Service, Centers for Disease Control, Protocol for Epidemiologic Studies of the Health of Vietnam Veterans (November 1983) at 1, 6-9 ("Health Study Protocol").[5]

[5] The two other studies—the "Vietnam Experience" study, to assess the "possible health effects of the general Vietnam experience," and the "Sarcoma/Lymphoma" or "Selected Cancers" study,

To isolate the effects of dioxin exposure, the Center needed to distinguish between groups of Vietnam veterans who were similar except for their level of dioxin exposure. *See supra* n.2. The Health Study Protocol proposed to use military records to divide a sample of Vietnam veterans into those who were likely exposed to herbicides in Vietnam and those likely not exposed and then to compare the health of the two cohorts. Health Study Protocol at 6-7, 10-15. The Center planned to review battalion journal files and morning reports to locate companies at various times during the Vietnam conflict and to determine the presence or absence of individuals within the company. Utilizing herbicide usage reports such as aircraft spraying records to estimate the location and timing of herbicide applications, the Center planned to fit veterans into the "likely exposed" or "likely not exposed" cohort "according to the measure of their company's distance in time and space from any herbicide applications." *Id.* at 6. To measure the possible health effects of dioxins, the Center would then compare the medical histories of "likely exposed" and "likely not exposed" veterans based on review of mortality records, health interviews, medical examinations, and laboratory tests. *Id.* at 20-25.

The Health Study Protocol cautioned that certain "obstacles" prevented the Center from adopting the "ideal" design for an Agent Orange cohort study, which would have compared one group free from all exposure to another group subjected to "meaningful" exposure to herbicides. These obstacles included the difficulty of defining "meaningful exposure" and the uncertainty about whether exposed veterans were comparable to unexposed veterans in other characteristics that might affect health. Most significant for purposes of these appeals, the Protocol

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to "evaluate the risk of contracting soft tissue sarcoma and lymphoma among Vietnam veterans (and/or those exposed to herbicides)"—have been completed and are not at issue in these appeals.

noted that the "uneven quality" of the military records, including gaps in company records and errors in herbicide usage records, meant that "the categorization of individuals with respect to their potential for herbicide exposure will be uncertain and will forever remain so." *Id.* at 6. The Health Study Protocol concluded that "[s]ince many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange Study, may be required. . . ." *Id.* at 11.

The Center's initial review, conducted from 1983 to 1986, confirmed its concern that inadequacies in the military documentation would likely make identification of appropriate cohorts impossible. Informed of these difficulties, OTA advised Congress in September 1985 that if the difficulties in evaluating exposure were not resolved, OTA might conclude that the [sic] "it is impossible to study the effects of Agent Orange." OTA subsequently suggested that the Center postpone any "major new phase" of its Agent Orange Study until it had devised an appropriate means of estimating exposure and recommend that instead of proceeding with the interviews of study subjects scheduled to begin in January 1986, the Center conduct a pilot study to test the methods and results of its initial exposure assessments. Accordingly, the Environmental Support Group of the United States Army and Joint Services developed a pilot study, at the Center's request, to identify "heavily exposed personnel." Completed in mid-1986, the pilot study ranked veterans based on their number of "hits," or opportunities for exposure to Agent Orange; veterans with the largest number of "hits" were classified as those most likely to have faced heavy exposure.[6]

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[6] A veteran received a score of one "hit" for each day that his company was located within 2 kilometers of a reported Agent Orange spray line applied within the previous 6 days.

In early 1986, the Agent Orange Working Group ("Working Group"), formed by the President to carry out his responsibilities under the 1979 Act, convened a Science Subpanel on Exposure Assessment ("Science Subpanel") to evaluate the Center's exposure assessment methods and review the results of the pilot study. In a May 26, 1986, letter to the Working Group, the Science Subpanel concluded that two problems jeopardized the Center's Agent Orange Study: first, the potential for "considerable" misclassification because of unit dispersion and incomplete records of spray operations; and second, the fact that the Center's records review showed that most veterans had never been exposed to a "hit," as defined by the Center, and thus "the paucity of clearly exposed combat veterans make it questionable whether a sufficient number can be assembled to conduct an epidemiological study of the type originally designed." The Science Subpanel noted that recent scientific advances might enable the Center more accurately to identify cohorts of likely exposed and likely unexposed veterans, but that given the problems with current identification methods, "any study of ground troops, which is dependent upon military records for the assessment of exposure to herbicides, [should] not be conducted without an additional method to verify exposure."

C. The TCDD Validation Study. Responding to the recommendations from OTA and the Science Subpanel not to proceed with a military records-based study without some independent verification, the Center developed a protocol to compare current serum TCDD levels in veterans' blood. Assuming TCDD survived in the blood for several years, the Center postulated that veterans who faced "heavy" exposure could be expected to have higher serum TCDD levels than lesser exposed veterans even twenty years after their exposure to Agent Orange.[7] The

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[7] Although the Center did not know the precise half-life of TCDD at the time it developed its TCDD protocol, it determined in the course of the study that TCDD has an average half-life of

Center used both the pilot study's "hit"-based exposure indices and veterans' self-reported exposure estimates to divide a set of Vietnam veterans into "low hit," "medium hit," and "high hit" subsets and, for comparison, also examined a group of non-Vietnam veterans of the same era.

The results of the TCDD study confirmed the Center's suspicions that neither military records nor self-reporting could adequately differentiate between veterans who were and were not likely exposed to Agent Orange in Vietnam. U.S. Department of Health Human Services, Centers for Disease Control, Comparison of Serum Levels of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin With Indirect Estimates of Agent Orange Exposure Among Vietnam Veterans: Final Report (August 1987) ("TCDD Report"). The Center found "no meaningful association" between veterans' current TCDD levels and the exposure indices developed through either military records or self-reporting.[8] *Id.* at 1. Besides failing to validate the use of military records as exposure indicators, the TCDD study reinforced the conclusion that ground troops faced little likelihood of "heavy" exposure to Agent Orange. *Id.* at 2. The Center thus concluded that it could not conduct the cohort Agent Orange Study that it had originally planned:

> The findings of this study and the conclusion from the Agent Orange Working Group Science Subpanel

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seven years. The half-life of a substance is "the time required by the body, tissue, or organ to metabolize or inactivate half the amount of a substance taken in." F.A. DAVIS, TABER'S CYCLOPEDIC MEDICAL DICTIONARY at 717 (1985).

[8] The Center controlled for differences such as age, race, region of current residence, body mass index, alcohol use, smoking history, and self-reported civilian occupational and home exposure to herbicides. *Id.* at 23. The study also considered the impact of other factors that might lead to study bias—group selection, laboratory error or measurement bias, variability in half-life, selection or participation bias, and sample size—and concluded that none of these factors likely influenced the results. *Id.* at 27-30.

> report on exposure assessment (June 1986) do not identify any method for using military records or self-reported exposure to distinguish between U.S. Army ground combat troops who were and were not exposed to Agent Orange in Vietnam, as would be needed for a cohort study of possible health effects.

Id. at 1.

In a review of the TCDD study, OTA agreed that "a large-scale epidemiological study to look for effects of Agent Orange in ground troops who served in Vietnam" was currently impossible, and cautioned that any future studies "should be narrowly focused on specific, testable hypotheses, and cannot have the aim of generalizability to all or most ground troops." *Id.* at 9. On October 29, 1987, the director of the Center reported to the Secretary the Center's concurrence with OTA and the Working Group that the Agent Orange Study "cannot be conducted" and that the Center had begun "the close-out process" for its Agent Orange Study.

D. The Secretary's decision. In December 1987, the Department of Medicine and Surgery in the Veterans Administration recommended a halt to all further studies of the effects of Agent Orange (other than the Air Force's Ranch Hand study). Because the results of the TCDD report "make it exceedingly unlikely that any method will satisfactorily distinguish between exposed and unexposed Vietnam veterans," the Department of Medicine and Surgery concluded that "a scientifically meaningful epidemiological study of the possible health effects of Agent Orange cannot be conducted."

On February 9, 1988, the Secretary sent the TCDD report, along with correspondence from OTA and the Working Group, to the Chairman of the House Committee on Veterans' Affairs. In a cover letter the Secretary stated that:

> Despite our efforts, . . . no one has successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151.[9] I must, therefore, advise you that no scientifically sound study can be undertaken and request that the [Veterans Administration] be relieved of the requirement to do this research. This opinion coincides with that of the Office of Technology Assessment, as expressed in their comments of September 1987, and with the June 3, 1987, comments of the interagency Agent Orange Working Group.

A week later, the Secretary formally notified the Chairman of the decision to discontinue work on the Center's Agent Orange Study. On February 19, 1988, in his third annual report to Congress on the status of the Center's three-part Health Study, the Secretary repeated his conclusion that "based on the results of the . . . TCDD Validation Study, . . . an [Agent Orange Study] cannot be conducted so as to achieve a scientifically sound conclusion regarding the possible adverse health effects of exposure of Vietnam veterans to Agent Orange." [10]

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[9] The Secretary described Ranch Hand veterans as "the sole group of veterans . . . available for the successful epidemiological investigation envisaged by the Congress."

[10] In accord with the Secretary's recommendation that any allocated but unexpended funds be reallocated to either "the U.S. Air Force's Ranch Hand Study's blood dioxin levels research or other research on Agent Orange and closely related subjects," Congress in 1988 transferred $3,000,000 of the unexpended funds for blood tests in the Ranch Hand study and $1,000,000 for "a survey of scientific evidence, studies, and literature" regarding the health effects of possible herbicide exposure in Vietnam, to be conducted by an independent scientific entity under contract with the VA, "pursuant to a law enacted after the date of the enactment of this Act." *See* § 1201 of Pub. L. No. 100-687, 102 Stat. 4105, 4125 (1988). Subsequently, in 1991, Congress authorized the National

Appellants thereafter filed suit, contending that the Secretary unlawfully abandoned the Center's Agent Orange Study based on the wrong legal standard, that the Secretary lacked authority to terminate the Agent Orange Study before submitting a health results report to Congress, and that his decision was contrary to the Administrative Procedure Act, 5 U.S.C. § 706. Following the district court's grant of summary judgment for appellees, appellants filed these consolidated appeals.

II.

In addressing appellants' challenges to the grant of summary judgment in favor of appellees, our review is *de novo*. *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995); *Shields v. Eli Lilly & Co.*, 895 F.2d 1463, 1466 (D.C. Cir. 1990). Thus, the limited questions before the court are whether the Secretary adopted a "permissible" interpretation of the 1979 and 1981 Acts, *see Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984), and, if so, whether, as a matter of law, the Secretary's decision in February 1988 to abandon the Center's Agent Orange Study was arbitrary and capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Dr. Pepper/Seven-Up Companies, Inc. v. FTC*, 991 F.2d 859, 862 (D.C. Cir. 1993). In reviewing the Secretary's decision to abandon the study, the court's task is to determine whether the Secretary "examine[d] the relevant data," and made a "rational connection between the facts found and the

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Academy of Sciences to review and evaluate the available scientific studies regarding the health effects of herbicide exposure and required the Secretary to enact regulations establishing a presumption that any malady correlated with herbicide exposure is service-related. Agent Orange Act of 1991, Pub. L. No. 102-4, 105 Stat. 11 (1991) (codified as amended at 38 U.S.C. § 1116 & note (Supp. IV 1992)).

choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations omitted); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. at 416. Given the nature of the scientific expertise brought to bear on the issue of whether to continue the Center's Agent Orange Study, the court's review is at its most deferential. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983).

A. Reporting "results". Appellants contend that the Secretary violated the statute by abandoning the Center's Agent Orange Study before reporting actual health results to Congress. Section 307(b)(2) of the 1979 Act provides:

> Not later than twenty-four months after the date of the approval of the protocol . . . and annually thereafter, the [Secretary] shall submit to the appropriate committees of the Congress a report containing (A) a description of the *results thus far obtained under the study* conducted pursuant to this subsection, and (B) such comments and recommendations as the [Secretary] considers appropriate in light of such results. [Emphasis added].

Appellants maintain that the word "results" in § 307 (b)(2) means substantive health results, and hence, that the Secretary lacked authority to abandon the Center's Agent Orange Study before reporting to Congress the Center's conclusions about adverse health effects of Agent Orange and other herbicides on Vietnam veterans. *See id.* § 307(a)(3) *as amended by* 1981 Amendments § 401 (a)(2) (Secretary may discontinue the study "after the submission of the first report under subsection (b)(2)"). The Secretary interprets "results" under § 307(b)(2) to include the progress made thus far to carry out the study and maintains that he fulfilled § 307(b)(2)'s requirement when he provided Congress with a progress report on February 13, 1986.

In reviewing the Secretary's interpretation of § 307 (b)(2), we apply the standard of review set forth in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984). Because, contrary to appellants' contentions, neither the plain language nor the structure of the statute makes clear Congress' intent to confine "results" to "health results" in mandating reports by the Secretary, the court must defer to the Secretary's interpretation if it "is based on a permissible construction of the statute." *Id.* The Secretary's interpretation accordingly invokes our deference.[11] Because the Secretary's interpretation of "results" is consistent with Congress' use of that term in the statute, *see* 1979 Act § 307(b)(2), and appellants' construction of congressional intent would lead to absurd results, the Secretary's interpretation withstands scrutiny.

The Secretary's interpretation that "results thus far obtained under the study" means the results of the Secretary's efforts pursuant to the statute is not an impermissible construction of § 307(b)(2). The word "results" is hardly a technical term of art, but one of common parlance subject to multiple meanings. Thus, "results" may include conclusions that the Secretary has reached in the course of efforts to carry out the Center's Agent Orange Study and are not, as appellants suggest, necessarily limited to "health results" produced by that study. The "result" of the TCDD study, for example, is the conclusion that current blood serum levels bear no relation to military records-based exposure assessments. The "results" of the pilot study are the index of "hit"-based

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[11] Although *Chevron* deference would not apply if the Secretary had adopted this interpretation solely for purposes of litigation, *see City of Kansas City, Mo. v. HUD*, 923 F.2d 188, 192 (D.C. Cir. 1991), the interpretation at issue appeared in the Secretary's February 13, 1986, report to Congress, in which he stated: "As required by Section 307 of Public Law 96-151 . . . I am sending you and your committee the first status report and its appendices" on the Agent Orange Study.

exposure assessments and the conclusion that most ground troops did not have the opportunity for heavy exposure to Agent Orange. Both studies led, in one sense, to "results . . . obtained under the study" since they followed the Secretary's approval of the Health Study Protocol and represented efforts to develop data that would enable the production of scientifically valid epidemiological conclusions.

Put otherwise, an epidemiological study on long-term health effects produces many types of "results" that the Secretary could report to Congress. The fact that the statute requires the Secretary to submit annual reports on the "results thus far obtained under the study" comports with the view that Congress wanted regular progress reports on the results of the Secretary's efforts, whether or not such reports contained substantive health results. *See* 1979 Act § 307(b)(2). Indeed, the Secretary's submission of various reports to Congress between 1986 and 1988 alerted Congress that the development of scientifically valid health results depended on the identification of reliable indices of cohort exposure. The language of § 307(a)(3) also supports the Secretary's interpretation; by allowing the Secretary to abandon the study after submission of the first report if he finds it unlikely that the study will yield "significant new information on the long-term health effects of exposure to dioxins," subsection (a)(3) appears to contemplate that the Secretary's first report may not itself contain information on adverse health effects.[12] *Id.* § 307(a)(3).

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[12] The fact that Congress directed the Secretary to consider various administrative actions based on the "results" reported under § 307(b)(2) does not make his interpretation of "results" unreasonable. *See id.* § 307(b)(2)(B), (b)(3). The statute requires the Secretary to submit "comments and recommendations [that the Secretary] considers appropriate in light of such results," *id.* § 307(b)(2)(B), and to give notice and comment of "actions, *if any*," that the Secretary proposes to take in response to the results. *Id.* § 307(b)(3) (emphasis added). The Secretary fulfilled

Appellants' contrary statutory arguments are unpersuasive. First, appellants contend that because the statute requires OTA to submit "updates" on the status of unapproved protocols, *id.* § 307(a)(2)(B)(ii), Congress must have intended "results" under § 307(b)(2) to mean more than a progress report. Although courts generally presume that " 'Congress acted intentionally and purposely' " when particular language in one section of a statute is omitted in another section. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)), the statutory differences between the reporting requirements imposed on OTA and the Secretary are consistent with the Secretary's interpretation of "results." OTA's "updates" on the status of protocol revisions reflect only the status of the Secretary's plans to conduct the study; because the Center's Agent Orange Study has not yet begun, the reports cannot contain its "results." The Secretary's reports, by contrast, reflect information gathered in the process of conducting the study, which can fairly be labeled "results thus far obtained under the study."

Similarly unpersuasive is appellants' second contention that the differences between the Agent Orange statute and a 1983 statute providing for an epidemiological study of the health effects of radiation exposure, Veterans Health Care Amendments of 1983, Pub. L. 98-160 § 601, 97 Stat. 1006-08 (1983) (codified as amended at 38 U.S.C. § 219 note (1988)) (the "1983 Act"), demon-

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the requirements of § 307(b)(2)(B) in his first and subsequent progress reports, when he informed Congress of the proposed TCDD study and its results, notified Congress of the Center's Agent Orange Study's abandonment, and recommended that the legislature reallocate unused funds. *See supra* n.10. Subsection (b)(3) makes clear that the Secretary need not recommend *any* "action" based on the study's "results." It is consistent with this subsection for the Secretary to recommend no rulemaking action, given the "result" that the effects of Agent Orange could not presently be ascertained.

strate that Congress intended to require the Secretary to provide "health results" in his reports pursuant to § 307(b)(2) of the 1979 Act. Although the 1983 Act explicitly gives the Secretary discretion not to conduct a study if he finds a scientifically valid study infeasible, *id.* § 601(a)(1)(B), the fact that the Secretary could not abandon the epidemiological study without developing a protocol and reporting some kind of results does not mean that the "results" reported must be "health results." Nor is the 1983 Act's requirement of reports on "the progress . . . and any results" of the radiation study, *id.* § 601(a)(5)(A), inconsistent with interpreting "results" as used in § 307(b)(2) of the 1979 Act to include data and conclusions other than "health results." Absent either a conflict between the 1983 Act and the Secretary's interpretation or a clear contrary meaning of the word "results," we will not read the 1983 Act to preclude the reasonable interpretation adopted by the Secretary. *Compare West Virginia University Hosp., Inc. v. Casey*, 499 U.S. 83, 99-101 (1991).[13]

Indeed, the reasonableness of the Secretary's interpretation is manifest in light of the implausibility of the alternative interpretation proposed by appellants. *See United States v. Wilson*, 112 S. Ct. 1351, 1354 (1992). Under their interpretation, Congress intended to require the Secretary to proceed with the Center's Agent Orange Study and present its "results" to Congress even when the Secretary knew that the inability to identify necessary data

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[13] Finally, while Congress' failure to consider the possibility that the study might not ultimately yield substantive health results cannot form the basis for an interpretation contrary to the plain meaning of a statute, *see West Virginia Univ. Hosp., Inc. v. Casey*, 499 U.S. at 100-01, where the Secretary's interpretation comports with the language of the statute and an alternative interpretation would produce absurd results, the fact that Congress did not specifically consider the issue is irrelevant. *See id.; see also Natural Resources Defense Council, Inc. v. EPA*, 725 F.2d 761, 770 (D.C. Cir. 1984).

would render the results scientifically useless. Not only do the 1981 Amendments and the Secretary's reports to Congress make clear that Congress knew that the underlying data was problematic, but the various reporting requirements in the statute highlight the unreasonableness of appellants' unsupported assumption that Congress intended the Secretary to devote resources to a study that the Secretary, the Center, the congressional OTA, and the President's Working Group had all concluded could not yield the valid scientific results mandated by statute. Other provisions in the statute also suggest that Congress did not intend the Secretary to conduct a study unless it was a scientifically valid one. Congress expressly required the Secretary to conduct the study pursuant to a protocol approved by the director of OTA. 1979 Act § 307(a)(2)(A)(i). The director of the OTA was to assess scientific validity in his approval or disapproval of the proposed protocol. *Id.* § 307(a)(2)(B)(i). Also, Congress directed the President to monitor the study for the purpose of assuring that the study was scientifically valid. *Id.* § 307(c). Assuming the accuracy of the Secretary's conclusion that a scientifically valid Agent Orange study was infeasible, in the absence of a clear statutory command, the Secretary was not required to proceed with a study that by all indications would not advance scientific knowledge solely to fulfill the obligation to report "results."

Because the language and purpose of the statute support the Secretary's interpretation of "results" as the progress made thus far in the Center's Agent Orange Study, we conclude that the Secretary satisfied his initial reporting obligation under § 307(b)(2) of the 1979 Act when he submitted a report to Congress on February 13, 1986, describing the results of efforts to carry out the epidemiological study.

B. The Standard. Appellants contend that the Secretary acted contrary to law because he decided to abandon

the study based on the repealed standard of the 1979 Act (focusing on individual veterans who "were exposed to . . . dioxins")[14] instead of the liberalized standard adopted in the 1981 Amendments (examining health effects that "may have resulted from exposure").[15] Appellants rely on the fact that in his February 9, 1988, letter to the Chairman of the House Committee on Veterans' Affairs, the Secretary reported that he had not "successfully identified a large enough group of Vietnam *known to have been exposed* to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151." They also point to the beginning of the Secretary's letter where he referred to the repealed legal standard in discussing the efforts made under the 1979 Act "[s]ince 1980." Appellants' emphasis on this language, however, overlooks other language in the Secretary's letter that demonstrates that he based his decision on concerns about scientific validity rather than compliance with the pre-1981 statutory mandate, that the numerous reports before the Secretary recommended abandoning the Center's Agent Orange Study because compliance with the 1981 mandate was not scientifically possible, and that the TCDD study confirmed that military records could not yield adequate exposure indices.

As appellants point out, a reviewing court "must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). It is equally true, however, that "we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974). Hence, even if some of the agency's remarks might appear erroneous when read in

[14] 1979 Act § 307(a)(1) (amended 1981).

[15] 1981 Amendments § 401(a)(1).

isolation, the court will uphold agency action that, "[c]onsidered in its entirety," is based on appropriate considerations and otherwise complies with relevant statutes and the Administrative Procedures Act. *District Lodge 64 v. NLRB*, 949 F.2d 441, 446 (D.C. Cir. 1991). Such consideration here indicates that the Secretary did not base his decision on the repealed statutory standard.

First, that the Secretary's decision focused on problems with the cohort study designed pursuant to the 1981 Amendments is evident from his letter's reference to the identification of a large enough *group* of veterans, as distinct from the focus of the original 1979 Act on individuals who had been exposed. The Secretary expressly incorporated by reference a separate statement by the Veterans' Administration's Department of Medicine and Surgery that refers to the 1981 standard and discusses the efforts to "estimate the likelihood" of exposure to Agent Orange. He noted, moreover, at the beginning of his letter that completion of the TCDD study "enabled the V[eterans'] A[dministration] to complete an attempt to determine directly and specifically whether exposure to Agent Orange had an adverse effect on the health of Vietnam veterans," thereby indicating that as addressed in the TCDD study, verification of exposure data remained the important factor under the 1981 standard. In context, therefore, the Secretary's reference to exposure suggests that the inability to distinguish exposure levels among different groups of veterans meant that he could not establish the data base necessary for a scientifically valid study.

Second, the Secretary attached to his February 9, 1988, letter to Congress OTA's September 1987 report and the Working Group's comments of June 3, 1987; both documents recommended abandonment of the Center's Agent Orange Study, not because of an inability to ensure that each study subject was exposed to Agent Orange, but because current identification methods provided no scientifically valid means of differentiating groups of veterans

based on the degree of exposure, and thus the long-term health effects of Agent Orange and other herbicides on the study subjects could not be assessed. OTA and the Working Group thus concluded that "no scientifically sound study can be undertaken."

Third, the Secretary also attached to his February 9, 1988, letter to Congress the TCDD validation study, which confirmed that compliance with the 1981 statutory mandate was not feasible because the Center was unable to classify groups of veterans based on their degree of exposure to Agent Orange and other herbicides. The Center compared individual hit scores as well as median TCDD levels by company, by the company in which the veteran spent the most time, and by the company in which the veteran had the most "hits." The Center concluded that neither individuals with higher "hit" scores nor companies with predicted higher levels of exposure had, on average, significantly higher TCDD levels in their blood, and therefore that it could not develop the data base needed for a cohort epidemiological study.

Viewing the Secretary's February 9, 1988, letter together with the documents that the incorporated by reference thus makes clear that notwithstanding the Secretary's reference to the inability to identify veterans "*known to have been exposed*" to Agent Orange and other herbicides, his decision to abandon the Center's Agent Orange Study rested on the inability to identify study cohorts based on the degree of exposure. Although Congress anticipated that the 1981 Amendments would remove the threshold problem of identifying individual veterans who were exposed to Agent Orange, 1981 S. REP. 26, 33, the amendments left in place the requirement that the study yield scientifically valid results. Appellants appear to ignore or underestimate the significance of the fact that even under the 1981 Amendments the epidemiological study depended on exposure data, and that the Center's Agent Orange Study relied on the ability to determine the degree of ex-

posure experienced by different groups of veterans. Thus, notwithstanding the Secretary's unfortunate choice of some words in his February 9 letter, the references noted by appellants cannot be divorced from the Secretary's references to "a large enough group" and the enclosed statement of the Department of Science and Medicine or fairly understood without regard to the supporting materials on which he relied in making his decision. For these reasons, we conclude that the Secretary did not rely on an improper legal standard in deciding to abandon the Agent Orange epidemiological study.

C. Abandoning the original Agent Orange Study. Because appellants' other challenges fail, the success of their appeals turns on whether, as a matter of law, the Secretary acted arbitrarily and capriciously in determining in February 1988 that a scientifically valid epidemiological study was infeasible. Appellants maintain that the "risk" of misclassification cannot alone make an epidemiological study scientifically invalid and that the Secretary had no evidence to support the conclusion that the degree of misclassification was sufficiently high to make valid scientific results unobtainable.

The statute vests the Secretary with broad discretion to abandon the entire epidemiological study if, after his initial report to Congress, the Secretary determines that the study will yield no useful scientific results.

> The study . . . shall be continued for as long after the submission of the first report under subsection (b)(2) as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

1979 Act § 307(a)(3) *as amended by* 1981 Amendments § 401(a)(2). Given this broad discretion, the scope of our review of the Secretary's decision to abandon one component of the Health Study Protocol is particularly limited.

See Kreis v. Secretary of Air Force, 866 F.2d 1508, 1514 (D.C. Cir. 1989) ("[i]t is simply more difficult to say that the Secretary has acted arbitrarily if he is authorized to act '*when he considers it necessary . . .*' than it is if he is required to act whenever a court determines that certain objective conditions are met") (emphasis in original). Applying this standard, we conclude that the Secretary did not act arbitrarily and capriciously in abandoning the Center's Agent Orange Study after determining, in view of the available reports, studies and recommendations, that it was unlikely to produce scientifically valid conclusions about the long-term effects of exposure to Agent Orange and other herbicides on Vietnam veterans' health. 1979 Act § 307(a)(3), (c).

The information available to the Secretary indicated that from its inception, the Center's Agent Orange Study was confronted with identification difficulties that persisted through an additional pilot study and completion of the TCDD study. The Center's Health Study Protocol anticipated that its records-based method of exposure assessment might require "modification, indeed even a recommendation not to proceed with an Agent Orange study . . . ." Health Study Protocol at 11. The initial review of military records confirmed the Center's concern that it might not succeed in identifying cohorts of veterans who faced a greater likelihood of exposure to Agent Orange and other herbicides than comparable cohorts of their peers and thus would have no way of distinguishing the health effects of exposure to Agent Orange or other herbicides, as needed for an epidemiological study. The congressional OTA and the President's Working Group supported this assessment. The pilot study, which the Center commissioned to evaluate its exposure assessment methods, highlighted the inexactitude in the military records and revealed not only that unit dispersion and inadequate spray records made classification difficult, but also that most veterans (other than the Ranch Hands) never had the opportunity for sig-

nificant Agent Orange exposure. The TCDD validation study, in turn, confirmed that the military records-based assessments bore no relationship to current (and therefore past) levels of Agent Orange in veterans' blood. With the evidence suggesting that the military records did not provide accurate exposure indices, and with no evidence that an alternative method existed to identify a sufficient number of veterans who were likely exposed to Agent Orange or other herbicides, the Secretary could reasonably conclude, in concurrence with the Center, OTA, and the Working Group, that the originally planned epidemiological Agent Orange Study was infeasible.

The fact that the TCDD study left open the possibility that military records might accurately identify exposed veterans at low levels of exposure does not alter this conclusion. Because the purpose of the TCDD study was to *validate* the records-based exposure indices, the study, while not ruling out the possibility that military records provided accurate exposure indices at low levels of exposure, did not provide the verification of low-level exposure indices that the Center, OTA, and the Working Group had deemed necessary to justify a cohort study using military records.

Appellants nevertheless fault the Secretary for his failure to determine precisely how much misclassification inheres in the military records. According to appellants, the Science Subpanel implicitly drew a line "on the epidemiological risk continuum" beyond which the degree of misclassification made scientific validity unachievable.[16] They

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[16] Appellants also rely on a statement in the 1986 Science Subpanel report that it "felt that an additional method to verify exposure is required" as indicating that the Secretary acted on the basis of amorphous "feelings" rather than evidence in the record. The Secretary, however, based his conclusion that an exposure verification method was necessary on more than the Science Subpanel's "feelings." OTA had similarly concluded that, because of misclassification problems, an independent method of

maintain that *Ethyl Corp. v. EPA*, 541 F.2d 1, 38-40 (D.C. Cir. 1976), and other cases require the Secretary to make this line explicit and to support his determination with evidence in the record. *Ethyl*, which involved an agency rule setting a particular numerical value for acceptable blood lead levels, 541 F.2d at 38, offers little guidance here. Whereas *Ethyl* addressed whether the agency had a rational basis for the chosen numerical value, the question in these appeals is whether the Secretary had a rational basis for determining that no known method existed to verify whether the military records-based assessments differentiated between exposed and non-exposed veterans in the way necessary for a cohort study. The TCDD study was designed, in part, to accomplish what appellants charge the Secretary should have done: determine the degree of correlation (and therefore the degree of misclassification) between military records and TCDD exposure. As the TCDD study illustrates, the Secretary has no way of knowing the precise degree of misclassification. The Secretary knows only that inaccuracies and imprecision in the military records make it impossible to determine whether a particular group of veterans is more likely to have been exposed to Agent Orange and other herbicides than a comparable cohort of their peers. That he did not pursue still other alternatives, at best vaguely identified by appellants, does not demonstrate that the Secretary acted unreasonably in concluding in February 1988 that the Center's Agent Orange Study should be abandoned.[17]

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exposure assessment or some means of verifying the records-based exposure estimates was needed. In addition, the TCDD study, which post-dated the Science Subpanel report, confirmed that military records did not give reliable estimates of exposure to Agent Orange among ground troops and that most ground troops had never faced meaningful exposure to Agent Orange or other herbicides.

[17] Appellants proffer the affidavit of Dr. Zena A. Stein, who states that "[m]isclassification problems, like those at issue in the

For these reasons we conclude that appellants have failed to show that when the Secretary made his decision, after extensive efforts to identify and classify the data required for an epidemiological study that focused solely on the long-term health effects of dioxin exposure, the Secretary acted unreasonably or contrary to law in abandoning the Center's Agent Orange Study. To the extent that Vietnam veterans as a group faced higher exposure to Agent Orange and other herbicides than other groups of veterans, the Center's Vietnam Experience and Selected Cancers Studies were designed, in part, to detect health effects that may have resulted from such exposure. In addition, the Air Force's Ranch Hands study was examining the one group of veterans who faced heavy exposure to Agent Orange and other herbicides. Based on the data

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[Center's] exposure study . . . do not necessarily invalidate any justification of the study." Affidavit at 6-7. Dr. Stein, however, concedes that "a valid study must meet a minimum threshold of probability and comparability" between exposed and unexposed cohorts with respect to the fact of exposure, amount and duration of exposure, and other personal characteristics and influences that might affect individuals' health. *Id.* at 2-4. Significantly, Dr. Stein does not criticize the methodology used by the Center in reviewing the military records, and she acknowledges that misclassification might preclude a valid Agent Orange Study if "the misclassification problems were much greater than anticipated and outlined in" the Health Study Protocol. *Id.* at 7.

Nor does appellants' assertion that the National Academy of Sciences has now proposed to conduct an Agent Orange Study based on military records discredit the Secretary's decision, which was made several years before the Academy issued its preliminary proposal. Moreover, in the single page from the proposal that appears in the record, the Academy acknowledges that it "does not know whether the approach it proposes will prove valid or whether new methods will identify a sufficient number of highly exposed Vietnam veterans for an epidemiologic study." National Academy of Sciences, Institute of Medicine, Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam (1993). This is hardly a criticism of the Secretary's approach, let alone the identification of a fundamental flaw in the studies and conclusions on which the Secretary relied.

available to the Secretary in February 1988, however, the Secretary could reasonably conclude that it was impossible to identify groups of Vietnam veterans who were similar except for their levels of dioxin exposure, as required for the cohort tests necessary to ascertain the health effects of dioxins through a scientifically valid Agent Orange Study.

Accordingly, because appellants have failed to present a material issue of fact or to demonstrate that appellees were not entitled to judgment as a matter of law as to whether the Secretary's decision was arbitrary, capricious, an abuse of discretion, or otherwise contrary to law, we affirm the grant of summary judgment to appellees.

[Filed Jun. 7, 1995]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 93-5404

THE AMERICAN LEGION,
Appellant

v.

EDWARD DERWINSKI, SECRETARY,
DEPARTMENT OF VETERANS AFFAIRS, *et al.*,
Appellees

and consolidated case No. 94-5013

Before: Edwards, *Chief Judge*, Randolph and Rogers, *Circuit Judges*.

ORDER

It is ORDERED, *sua sponte*, that the opinion filed herein on April 25, 1995 is amended, as follows:

In the caption of the consolidated case

delete

"Vietnam Veterans of America; Harold A. Butler; Carol Ridolfi-Delaney; Marel J. Macki; Beverly Nehmer,"

substitute

"William (Bill) Atwell; Harold A. Butler; Carol Delaney-Ridolfi; Julio Gonzales; Marel J. Macki;

Beverly Nehmer; Daniel Orta; Paul L. Sutton," to the listing of appellants.

Per Curiam

FOR THE COURT:
MARK J. LANGER
Clerk

By: /s/ Illegible
Deputy Clerk

APPENDIX B

[Filed Jul. 19, 1993]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Actions
No. 90-1808 SSH
No. 90-1809 SSH
(consolidated)

THE AMERICAN LEGION,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary,
United States Department of Veterans Affairs, *et al.*,
Defendants.

VIETNAM VETERANS OF AMERICA, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary,
United States Department of Veterans Affairs, *et al.*,
Defendants.

OPINION

Before the Court are defendants' motion to dismiss or, in the alternative, for summary judgment; plaintiffs' motion to supplement the record; plaintiffs' second motion to supplement the record; plaintiffs' motion for discovery; defendants' motion for a protective order staying dis-

covery pending a ruling on defendants' dispositive motion; and the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*.[1] Upon consideration of the motions, the Court grants defendants' motion for summary judgment, grants in part plaintiffs' motion to supplement the record, and denies the remaining motions.

Summary judgment may be granted only if the pleadings and evidence "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In considering a summary judgment motion, all evidence and the inferences to be drawn from it must be considered in a light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Summary judgment cannot be granted "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Although findings of fact and conclusions of law are unnecessary in ruling on a summary judgment motion, the Court sets forth its reasoning. *See* Fed. R. Civ. P. 52(a).

Background

Plaintiffs are The American Legion, Vietnam Veterans of America, and nine individually-named Vietnam veterans and widows of veterans.[2] Defendants are the Secretaries of the Department of Veterans Affairs (VA) and the Department of Health and Human Services (HHS),

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[1] On September 3, 1992, the Magistrate Judge issued a Report and Recommendation that resolved seven of the 11 pending nondispositive motions. The Magistrate Judge recommended that the Court resolve the remaining four nondispositive motions in conjunction with the dispositive motion. Both sides agree with this recommendation, as does the Court.

[2] The individual plaintiffs are Bill Atwell, Harold A. Butler, Carol Delaney-Ridolfi, Julio Gonzales, Marel J. Macki, Beverly Nehmer, Laura O'Callaghan, Daniel Orta, and Paul L. Sutton.

the Directors of the Centers for Disease Control (CDC) and its Center for Environmental Health and Injury Control, and the United States. Plaintiffs challenge defendants' action terminating a congressionally-mandated study to investigate any long-term health effects in Vietnam veterans that may have resulted from exposure to phenoxy herbicides, including Agent Orange. *See* Pub. L. No. 96-151, 93 Stat. 1097 (1979) (amended 1981, 1984), 38 U.S.C. § 219 note.[3] Plaintiffs seek a declatory judgment that defendants' decision to cancel the study violated the authorizing statute and the Administrative Procedure Act (APA), 5 U.S.C. § 706. Plaintiffs also seek an injunctive order directing defendants to conduct the study.[4]

For two years following enactment of the authorizing statute, the VA's contractor for the study encountered significant difficulties identifying veterans who had actually been exposed to herbicides. As a result, in 1981 Congress loosened the requirement of actual exposure to allow the study to commence. *See* Pub. L. 97-72, 95 Stat. 1061 (1981). In January 1983, the VA entered into a contract with the CDC to design and execute the study. The CDC developed a protocol intended to iden-

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[3] The statute requires in part that the Secretary of Veterans Affairs:

> design a protocol for and conduct an epidemiological study of any long-term adverse health effects in [Vietnam veterans] as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides.

38 U.S.C. § 219 note (a) (1) (A).

[4] In addition, plaintiffs seek an order requiring the VA, after completing the study, to review and amend disability and death compensation regulations as the study results warrant, and to readjudicate veterans' claims that have been denied but which might raise issues in light of the study's results or the amended regulations.

tify discrete cohorts of veterans who were and were not likely to have been exposed to Agent Orange in Vietnam. The CDC planned to determine whether those likely to have been exposed suffered from any distinct health effects. By early 1984 the congressional Office of Technology Assessment (OTA) had approved the CDC's protocol as required by the authorizing statute. 38 U.S.C. § 219 note (a)(2)(A)(i).

The CDC had qualified the study's potential within the protocol, noting that "[s]ince many of the proposed procedures are untested, modifications, indeed even a recommendation not to proceed with the Agent Orange study, may be required after pilot assessments." Erickson Decl. Ex. A at 11. Working with the United States Army and Joint Services Environmental Support Group to match military records of troop locations and herbicide spraying, the CDC found that the records were more deficient than it had anticipated. The data indicated that troops were often dispersed 20 kilometers from the main company's location records. In addition, records contained gaps of company locations for various days. Eventually, the CDC sought to adjust the original protocol in 1985. In response to the CDC's proposed changes, the OTA demanded a revised protocol. Furthering the OTA position, in January 1986, the chairmen of the House Veterans' Affairs Committee and the Senate Committee on Veterans' Affairs requested the CDC to suspend activity on the principal study until after the OTA approved a new protocol.

In addition to the mandated OTA oversight, the authorizing statute charged the President with monitoring the Agent Orange exposure study to assure its scientific validity. 38 U.S.C. § 219 note (c). As a result, an interagency council of Cabinet and subcabinet level officers known as the White House Domestic Policy Council (DPC) had organized a subgroup, the Agent Orange Working Group (AOWG). In early 1986, following the

OTA's demand for a new protocol, the AOWG's Science panel convened a Subpanel on Exposure Assessment (Subpanel) to review the status of the study. The June 1986 Subpanel report and a companion pilot assessment disclosed a considerable potential for misclassification of exposed and non-exposed veterans. The study confirmed the difficulty of identifying reliable cohorts to examine. Subsequently, the AOWG Science panel concluded that an exposure study based on military records alone was not scientifically valid. The AOWG Science panel recommended that the CDC develop an independent verification method to determine the likelihood of veterans' exposure to Agent Orange.

Adopting the AOWG Science panel's recommendation in the summer of 1986, the CDC developed a validation study to verify the accuracy of exposure estimates based on military records. By measuring the 2,3,7,8-TCDD (dioxin) level in blood serum, the CDC could reasonably determine previous exposures to phenoxy herbicides. The study results showed no correlation between the military records' estimates of exposure to Agent Orange and the veterans' blood dioxin levels.

Based on the recommendation of the AOWG Science panel and the results of the blood dioxin verification study, the CDC concluded that a scientifically valid exposure study could not be performed. In August 1987, after reviewing these findings, the OTA Agent Orange Advisory Panel, the AOWG Science panel, and the AOWG all recommended that the Agent Orange exposure study be cancelled. On October 9, 1987, the AOWG initiated the process for terminating the contracts of the CDC study. The DPC approved the AOWG recommendation on November 5, 1987. The AOWG informed the congressional committees that the study had "proved scientifically impossible to do." Beach Decl. Exs. G and H at 1.

Subsequently, on November 24, 1987, the VA requested a written report from the CDC regarding the recommenda-

tion that no scientifically valid study could be performed.[5] In December 1987, the VA Department of Medicine and Surgery conducted an independent review of the CDC's findings and endorsed the recommendation. The VA Administrator notified the House Veterans' Affairs Committee and the Senate Committee on Veterans' Affairs in a February 9, 1988, letter that:

> no one has successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151. I must, therefore, advise you that no scientifically sound study can be undertaken and request that the VA be relieved of the requirement to do this research.

Hobson Decl. Ex. E at 1-2. On February 17, 1988, the VA notified the congressional committees that funds previously appropriated for the Agent Orange study would revert to the Treasury Department. Subsequently, Congress ordered those funds shifted to other veterans' studies "upon cancellation of that contract." Pub. L. No. 100-687, § 1201, 102 Stat. 4105, 4125 (1988).

Discussion

In response to plaintiffs' claims contesting the termination of the study, defendants contend that they are entitled

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[5] Defendants cite this information as evidence that the VA made the ultimate decision to cancel the study. *See* Defendants' Reply to Plaintiffs' Memorandum in Opposition to Defendants' Motion for Summary Judgment at 6. However, this material does not appear within the administrative record submitted by defendants or the supplemental exhibits which they provide. Rather, this information is presented in Plaintiffs' Exhibit 28. The Court, however, supplements the record with Plaintiffs' Exhibit 28. *See infra* part II.B.

to summary judgment on two grounds.[6] First, defendants claim that Congress ratified the decision to cancel the study. Second, they argue that their actions were rational and otherwise in accordance with law, and therefore did not violate the APA. The Court first addresses defendants' ratification claim and then examines the alleged APA violations.

I. *Congressional Ratification*

Defendants claim that they are entitled to summary judgment because Congress approved the decision to cancel the exposure study in 1988. Defendants contend that Congress ratified the cancellation when it transferred the funds originally appropriated for the Agent Orange exposure study to other veterans' studies. Plaintiffs assert that defendants have failed to satisfy the heavy burden required to demonstrate ratification by appropriation.

In *Associated Electric Cooperative, Inc. v. Morton*, this Circuit held that "ratification by appropriation will not be found unless prior knowledge of the specific disputed action can be clearly demonstrated and the appropriation plainly shows 'a purpose to bestow the precise authority which is claimed'." *Associated Elec. Coop. Inc. v. Morton*, 507 F.2d 1167, 1174 (D.C. Cir. 1974) (citations omitted), *cert. denied*, 423 U.S. 830 (1975). When Congress reappropriated the funds from the Agent Orange study, it made no reference to repealing the authorizing statute. Pub. L. No. 100-687, § 1201, 102 Stat. 4105, 4125 (1988). Viewing the evidence in the light most favorable

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[6] Defendants also move to dismiss, claiming that the CDC's design and methodology choices are committed to agency discretion and not subject to judicial review. *See* 5 U.S.C. § 701(a)(2). Plaintiffs deny that they challenge the legality of the CDC's actions. Although the Court finds that plaintiffs do challenge the CDC's actions, they do so only in an effort to establish that defendants acted arbitrarily and capriciously in concluding that no Agent Orange study could be scientifically valid. Therefore, the Court denies defendants' motion to dismiss.

to plaintiffs, the Court finds that there is a genuine issue of material fact in dispute as to whether Congress had the requisite purpose to repeal the substantive law which authorized the study. Thus, the Court concludes that summary judgment on the basis of defendants' congressional ratification argument is inappropriate.[7]

II. *Alleged Violations of the APA* [8]

Under the APA, reviewing courts generally must examine "final agency action." 5 U.S.C. § 704. Deferring judicial intervention until after the agency's final action permits the full exercise of the administrative process.

"[T]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). The final agency action in this case may be characterized as an informal one, and the Court will set it aside only if it is " 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements." *Citizens To Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971) (*citing* 5 U.S.C. § 706(2)(A), (B), (C), (D)). This standard is highly deferential. *See, e.g., Motor*

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[7] Upon consideration of the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*, the Court upholds the order because it is not "clearly erroneous or contrary to law." *See* Fed. R. Civ. P. 72(a).

[8] Because neither the authorizing statute nor legislative history indicates any congressional intent to create a private cause of action under the Agent Orange exposure study statute, the Court does not recognize such a right. *See Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 13-15 (1981). As a result, plaintiffs' claims that defendants violated the authorizing statute are governed by the APA. 5 U.S.C. § 706(2)(A).

Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Moreover, reviewing courts are to defer to reasonable agency interpretations of statutory schemes when the authorizing language is silent or ambiguous. *See Chevron, U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 843 (1984).

As a threshold matter, the Court examines the parties' dispute regarding which governmental body made the final decision to cancel the Agent Orange exposure study. The Court then addresses the parties' conflict over the adequacy of the administrative record. Finally, the Court considers whether the decision to cancel the study was arbitrary, capricious, or otherwise not in accordance with law.

A. Final Agency Action

First, plaintiffs contend that determining which body made the decision to cancel the study, the DPC or the VA, is a genuine issue of material fact that precludes summary judgment. In their initial statement of material facts, defendants claimed that the DPC made the decision to cancel the study. In their amended statement of material facts, however, defendants withdrew this contention. Instead, they assert that the VA Administrator's decision to terminate the study was the final agency action reviewable by this Court.[9] Plaintiffs, however, claim that during

[9] The Court rejects plaintiffs' attempt to estop defendants from amending their statement of facts. Plaintiffs argue that if defendants recant earlier statements they thereby create a material issue of fact. *See Pyramid Sec. Ltd. v. IB Resolution, Inc.*, 924 F.2d 1114, 1123 (D.C. Cir. 1991) ("Courts have long held that a party may not create a material issue of fact simply by contradicting its prior sworn testimony." (citation omitted)), *cert. denied*, 112 S. Ct. 85 (1991). Defendants claim that their misstatements do not contradict sworn declarations but were "arguments contained in defendants' legal memoranda" that "resulted from honest error" on counsel's part. *See* Defendants' Opposition to Plaintiffs' Motion to Estop Defendants at 15. It is undisputed that the VA

a meeting on November 5, 1987, the DPC made the decision to cancel the Agent Orange exposure study. This DPC decision, plaintiffs assert, violates the statutory authority which restricts cancellation of the study to the VA Administrator. *See* 38 U.S.C. § 219 note (a)(3).[10] At the least, they claim that defendants' reversal regarding the finality of the DPC action is sufficient to create a genuine issue of material fact.

It is well settled that courts generally review final agency action which is the last, legal administrative action. *See, e.g., Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). Courts are averse to reviewing action prior to agency completion. Viewing the facts in the light most favorable to the plaintiffs, the Court assumes that the DPC made a decision to cancel the CDC study and to notify Congress thereof. However, this action by the DPC is not inconsistent with the VA's retention and execution of the final, legal authority to cancel the Agent

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Administrator had the sole statutory authority to cancel the study and that his letter of February 9, 1988, was the final action taken in announcing the cancellation. As such, defendants "offer persuasive reasons for believing the supposed correction." *Pyramid*, 924 F.2d at 1123. Therefore, the Court permits defendants' proposed amendments.

Even if the Court were to estop defendants from amending their statement of facts, the Court would still find that there is no genuine issue of material fact in dispute. The Court finds that, regardless of what the Beach declaration states that the DPC decided to tell Congress or how the Hobson declaration characterizes the VA's action, the VA nevertheless ultimately exercised its sole legal authority to cancel the study.

Plaintiffs also raise other facts purportedly in dispute, but the Court finds that they are likewise not material.

[10] The cancellation provision reads in part: "The study . . . shall be continued for as long . . . as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." 38 U.S.C. § 219 note (a)(3).

Orange exposure study. Following the DPC decision, on November 24, 1987, the VA requested a written report from the CDC with all data recommending cancellation of the study.[11] In December 1987, the VA Department of Medicine and Surgery conducted an independent study of the CDC's findings and concluded that no Agent Orange exposure study could be performed in a scientifically valid manner. The VA Administrator informed Congress in a February 9, 1988, letter of the decision that no scientifically valid study could be performed.

Had the VA not acted following the DPC decision to cancel, plaintiffs might have had a valid claim that the DPC made the final decision to cancel the study. However, the record demonstrates that the VA exercised the ultimate, binding decision to cancel the Agent Orange exposure study in February 1988. As plaintiffs and defendants recognize, the VA had the sole legal authority to terminate the Agent Orange exposure study. At the time that he chose to cancel the study, the VA Administrator could have used his power to continue the study regardless of the DPC finding. Moreover, even assuming that the DPC cancelled the CDC study, the VA could have initiated a new round of protocols to pursue the Agent Orange exposure study. Thus, the VA decision terminating the study was the final agency action, and it is reviewable by this Court. *See* 5 U.S.C. § 704.

B. *Adequacy of the Administrative Record*

Secondly, plaintiffs claim that even if the VA made the final agency action, the administrative record is insufficient for effective judicial review and they seek to amend it. Plaintiffs seek to augment the record with supplemental documents and declarations which they claim demonstrate that defendants acted arbitrarily and

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[11] *See supra* note 5.

capriciously in concluding that no scientifically valid study could be conducted. Plaintiffs also assert that some of the proposed supplemental exhibits reveal defendants' failure to consider relevant factors. Others, they contend, demonstrate that defendants relied on irrelevant considerations. Still others, according to the plaintiffs, provide important background information for the Court. Additionally, plaintiffs seek discovery primarily to inquire into any possibly improper DPC or White House pressures on the VA decision to cancel. Defendants contend, however, that the administrative record before the Court is adequate for effective judicial review.[12]

It is well established that courts are generally to review agency action based solely on the administrative record provided by the agency. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."); *Environmental Defense Fund, Inc. v. Costle*, 657 F.2d 275, 286 (D.C. Cir. 1981) ("There is no occasion for a judicial probe beyond the confines of a record which affords enough explanation to indicate whether the agency considered all relevant factors."). In addition, that record must be the one that was before the decision-maker. *See, e.g., Walter O. Boswell Memorial Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision.").

Courts have identified certain limited occasions that may allow the addition of supplemental information to the record. Among other reasons, the record may be supplemented:

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[12] Asserting that some documents were inadvertently omitted from the original record, defendants supplemented the record with five (Plaintiffs' Exhibits 14, 16, 23, 25, and 27) of the 29 documents plaintiffs seek to admit as well as two other documents.

> (1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency considered evidence which it failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly. . . .

Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989) (footnote omitted). Moreover, the Ninth Circuit has found that the record may be supplemented when additional information "fully explicate[s] [the agency's] course of conduct" in reaching its decision. *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).

The Court finds that the approximately 2,000-page administrative record contains the VA Administrator's articulated explanation for his decision to cancel the exposure study. The record also includes the respective recommendations of the VA Department of Medicine and Surgery, the CDC, the OTA, and the AOWG Science Subpanel which were before the VA Administrator when he chose to terminate the study. The record includes, but is not limited to, evidence that defendants considered the relevant factors in selecting which veterans to study and in choosing the geographical area and time period to examine. It also contains defendants' reasoning for the necessity and relevance of the blood dioxin verification study. Plaintiffs' supplemental documents and declarations primarily challenge the scientific merits of the decision to cancel. Plaintiffs' other exhibits fail to contribute information pertinent to defendants' action or provide only peripheral background information. Accordingly, plaintiffs' motion to add documents to the record is largely denied.

The Court does, however, grant in part plaintiffs' motion to supplement the record. Plaintiffs' Exhibit 28 provides relevant information regarding the chain of events

in the VA's decision to terminate the study. The decision to terminate the Agent Orange exposure study involved numerous agencies and much interagency communication. Included in Plaintiffs' Exhibit 28 is the VA's request for a written report containing the CDC's data, which aids in fully explicating the VA's "course of conduct." *See Asarco, Inc.*, 616 F.2d at 1160. No other exhibit offered by plaintiffs yields information not already in the record regarding central steps in the VA's decisional process. Thus, for the limited purpose of more fully explicating the VA's decision, the Court supplements the administrative record only with Plaintiffs' Exhibit 28.[13] The Court therefore grants in part and denies in part plaintiffs' motion to supplement the record and denies plaintiffs' second motion to supplement the record.

Courts may grant discovery in agency review cases when, for example, there is a "strong showing of bad faith or improper behavior." *Citizens To Preserve Overton Park*, 401 U.S. at 420. Plaintiffs, however, submit no evidence that the VA Administrator relied on irrelevant factors in cancelling the study. They proffer only speculation that the DPC or the White House exerted pressure on the VA Administrator. Accordingly, the Court denies plaintiffs' motion for discovery.

C. *Defendants' Actions Were Not Arbitrary and Capricious Nor in Violation of the Law*

Plaintiffs claim that defendants violated the APA by acting arbitrarily and capriciously and not in accordance with law. *See* 5 U.S.C. § 706(2)(A). The Court disagrees. As noted, Rule 52(a) of the Federal Rules of Civil Procedure specifically makes findings and conclusions unnecessary in ruling on a motion for summary

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[13] Even without Exhibit 28 in the administrative record, the Court would still hold that the VA made the final decision to cancel the Agent Orange study.

judgment, but the Court elects to address plaintiffs' more meritorious arguments.

1. *Not Arbitrary and Capricious*

Among the actions which plaintiffs challenge is defendants' determination that a scientifically valid study would require independent verification to corroborate the exposure estimates based on military records. Additionally, plaintiffs challenge defendants' finding, based on the blood dioxin study, that no scientifically valid study could be performed. Finally, plaintiffs challenge the decision to cancel the study. Defendants argue that the scientific conclusions and the VA's decision to cancel the study were rational and reasoned.

The scope of review is "narrow" under the arbitrary and capricious standard. *Motor Vehicle Mfrs. Ass'n, Inc.*, 463 U.S. at 43. The reviewing court presumes agency action to be valid. *Citizens To Preserve Overton Park*, 401 U.S. at 415 ("Certainly, the [agency's] decision is entitled to a presumption of regularity."). Moreover, a court may not substitute its judgment for that of the agency. *Id.* at 416. Indeed, the Court need not decide if the decision to cancel the study is supported by a preponderance of the evidence or even whether it is supported by substantial evidence. Rather, the Court must sustain the decision if it has a rational basis in the evidence. *See Ethyl Corp. v. EPA*, 541 F.2d 1, 37 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976).

In addition, under the APA a reviewing court must not only consider the final agency action but also "preliminary" and "intermediate" agency actions. 5 U.S.C. § 704. As a result, the Court examines challenges to the scientific conclusions on which the VA relied. In examining such challenges to decisions involving an agency's area of special expertise at the frontiers of science, "a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. National Resources Defense*

Council, 462 U.S. 87, 103 (1983); *see also Ethyl Corp.*, 541 F.2d at 36 ("We must look at the [agency's] decision not as the chemist, biologist or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.").

One of the scientific conclusions that the plaintiffs challenge is the CDC's 1986 rejection of the scientific validity of exposure estimates based on military records. Plaintiffs contend that this conclusion is an arbitrary reversal from the CDC's original protocol. However, in concluding against sole reliance on the military records, the CDC considered the results of the June 1986 Subpanel report. The Subpanel report delineated three years of new data compiled by abstracting military records in an effort to match troop locations with herbicide spraying. This additional evidence on the unreliability of the military records established a rational basis for the CDC's 1986 decision that exposure estimates based on such records would not create scientifically valid exposure cohorts.

Plaintiffs also challenge the CDC's blood dioxin verification method and its finding that the study results indicated no scientifically valid exposure study could be performed. At the heart of plaintiffs' arguments, however, is a challenge to the scientific merit of the CDC's research rather than the rationality of its conclusion. Assuming, but not deciding, that plaintiffs may challenge the scientific merit, *see supra* note 6, the Court finds that the CDC's methodology and research exhibit reasoned decisionmaking and provide a rational basis for defendants' conclusion that a meaningful scientific study could not be performed.

In addition, plaintiffs also challenge the VA's decision to cancel the study. As noted, the authorizing statute provides that "[t]he study . . . shall be continued for as long . . . as the Administrator may determine reasonable

in light of the possibility of developing through such study significant new information on the long-term health effects of exposure to dioxins." 38 U.S.C. § 219 note (a)(3). Having considered the evidence and recommendations of the AOWG, the CDC, the OTA Agent Orange Advisory Panel, and the VA's Department of Medicine and Surgery, the Administrator concluded that no scientifically valid study could be performed. The Court finds that this decision to cancel was reasoned and rational. Thus the Court finds that neither the scientific conclusions leading up to the VA's decision to terminate the study nor the Administrator's final decision were "arbitrary and capricious." [14]

2. *Not Otherwise in Violation of Law*

Plaintiffs also assert that defendants' interpretation of the statutory scheme violates the authorizing statute and consequently the APA's requirement that agency action be in accordance with law. *See* 5 U.S.C. § 706(2)(A). They contend that defendants' failure to submit an initial report to Congress explaining the "results thus far obtained under the study" is one such violation. 38 U.S.C. § 219 note (a)(3), (b)(2). Defendants claim that in mandating such a report, Congress did not intend to require commencement of the study if no such study could be conducted with scientific validity. Instead, defendants argue that Congress required the report as a progress account, which defendants submitted.

"[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. The Court finds that defendants' construction of the statute was a "reasonable interpretation" of the provision. *Id.* at 844. The statute requires the President to assure the study's scientific validity. 38 U.S.C. § 219 note (c). In

[14] The Court rejects as meritless plaintiffs' other claims that defendants acted in an arbitrary and capricious manner.

light of this requirement, defendants' interpretation of the mandated report as a program update is reasonable. Thus, the Court finds that defendants committed no statutory violation that would breach the APA.[15] Accordingly the Court grants defendants' motion for summary judgment.[16]

Conclusion

For the reasons stated, the Court grants in part plaintiffs' motion to supplement the record as to Plaintiffs' Exhibit 28 and denies the remainder of the motion. The Court also denies plaintiffs' second motion to supplement the record, plaintiffs' motion for discovery, and the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*. However, finding no genuine issue of material fact in dispute and finding in favor of defendants as a matter of law, the Court grants defendants' motion for summary judgment. An appropriate Order accompanies this Opinion.

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States District Judge

Date: Jul. 19, 1993

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[15] The Court rejects plaintiffs' other statutory violation claims.

[16] As the Court grants defendants' motion for summary judgment, it denies as moot defendants' motion for a protective order staying discovery pending a ruling on the dispositive motion.

APPENDIX C

[Filed Jul. 19, 1993]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Actions
No. 90-1808 SSH
No. 90-1809 SSH
(consolidated)

THE AMERICAN LEGION, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary, United States Department of Veterans Affairs, *et al.*,
Defendants.

VIETNAM VETERANS OF AMERICA, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary, United States Department of Veterans Affairs, *et al.*,
Defendants.

ORDER

For the reasons stated in the Court's accompanying Opinion, it hereby is

ORDERED, that plaintiffs' motion to supplement the record is granted in part and denied in part, and the ad-

ministrative record is supplemented with Plaintiffs' Exhibit 28. It hereby further is

ORDERED, that plaintiffs' second motion to supplement the record is denied. It hereby further is

ORDERED, that plaintiffs' motion for discovery is denied. It hereby further is

ORDERED, that the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae* is denied. It hereby further is

ORDERED, that defendants' motion for a protective order staying discovery pending a ruling on defendants' dispositive motion is denied as moot. It hereby further is

ORDERED, that defendants' motion for summary judgment is granted and the case is dismissed.

SO ORDERED.

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States District Judge

Date: Jul. 19, 1993

APPENDIX D

[Filed Apr. 25, 1995]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 93-5404

THE AMERICAN LEGION,
Appellant

v.

EDWARD DERWINSKI, Secretary,
Department of Veterans Affairs, *et al.*,
Appellees

And Consolidated Case 94-5013

ORDER

It is ORDERED on the Court's own motion, that the Clerk shall withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. See D.C. Cir. R. 41(a) (January 1, 1994). This instruction to the Clerk is without prejudice to the right of any party at any time to move for expedited issuance of the mandate for good cause shown.

FOR THE COURT:
MARK J. LANGER
Clerk

By: /s/ Eva Brown
Deputy Clerk

APPENDIX E

SUPREME COURT OF THE UNITED STATES
OFFICE OF THE CLERK
Washington, DC 20543

WILLIAM K. SUTER
Clerk of the Court

Area Code 202 479-3011

June 19, 1995

Mr. Gershon M. Ratner
National Veterans Legal
2001 S Street, Suite 610
Washington, DC 20009

Re: American Legion
v. Jesse Brown, Secretary of
Veterans Affairs, et al.
Application No. A-959

Dear Mr. Ratner:

The application for an extension of time within which to file a petition for a writ of certiorari in the above-entitled case has been presented to the Chief Justice, who on June 19, 1995, extended the time to and including August 23, 1995.

* * * *

Sincerely,

WILLIAM K. SUTER
Clerk

By /s/ Troy D. Cahill
TROY D. CAHILL
Assistant Clerk

APPENDIX F

STATUTORY PROVISIONS

Veterans' Health Programs Extension and Improvement Act of 1979, Pub. L. 96-151, § 307 (as amended):

38 U.S.C.A. § 527 Note

"(a)(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such study, the Administrator may expand the scope of the study to include an evaluation of any long-term adverse health effects in humans of such service as such health effects may result from other factors involved in such service, including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. The Administrator may also include in the study an evaluation of the means of detecting and treating adverse health effects found through the study.

"(B) The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such review and analysis, the Administrator may expand the scope of such review and analysis to include a review and analysis of the literature covering other studies relating to whether there may be

long-term adverse health effects in humans from other factors involved in service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict or in other comparable situations involving one or more of the factors described in the second sentence of subparagraph (A). The Administrator may also include a review and analysis of the means of detecting and treating adverse health effects found through any study covered by either such review and analysis.

"(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

"(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

"(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

"(ii) In the event that the Director has not approved such protocol during the one hundred and eighty days following the date of the enactment of this Act [Dec. 20, 1979], the Director shall (I) submit to the appropriate committees of the Congress a report describing the reasons why the Director has not given such approval, and (II) submit an update report on such initial report each sixty days thereafter until such protocol is approved.

"(C) The Director shall submit to the appropriate committees of the Congress, at each of the times specified in the second sentence of this subparagraph, a report on the Director's monitoring of the conduct of such study

pursuant to subparagraph (A)(ii). A report under the preceding sentence shall be submitted before the end of the six-month period beginning on the date of the approval of such protocol by the Director, before the end of the twelve-month period beginning on such date, and annually thereafter until such study is completed or terminated.

"(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the first report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

"(b)(1) Not later than twelve months after the date of the enactment of this Act [Dec. 20, 1979], the Administrator shall submit to the appropriate committees of the Congress a report on the literature review and analysis conducted under subsection (a)(1).

"(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations for administrative or legislative action, or both, as the Administrator considers appropriate in light of such results.

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure

Compensation Standards Act, [section 5 of Pub.L. 98-542, set out as a note under section 1154 of this title] for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such section. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.

"(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code [now section 1710(a)(5) of this title], should be extended beyond the expiration period specified by section 610(e)(3) of such title [now section 1710(e)(3) of this title].

"(c) For the purpose of assuring that any study carried out by the Federal Government with respect to the adverse health effects in humans of exposure to dioxins is scientifically valid and is conducted with efficiency and objectivity, the President shall assure that—

"(1) the study conducted pursuant to subsection (a) is fully coordinated with studies which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to the adverse health effects in humans of exposure to dioxins; and

"(2) all appropriate coordination and consultation is accomplished between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of the study carried out pursuant to subsection (a), in a design, conduct, monitoring, or evaluation of such dioxin-exposure studies.

"(d) There are authorized to be appropriated such sums as may be necessary for the conduct of the study required by subsection (a)."

Pub. L. 96-151, § 307, Dec. 20, 1979, 93 Stat. 1097:

AGENT ORANGE STUDY

SEC. 307. (a)(1) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of persons who, while serving in the Armed Forces of the United States during the period of the Vietnam conflict, were exposed to any of the class of chemicals known as "the dioxins" produced during the manufacture of the various phenoxy herbicides (including the herbicide known as "Agent Orange") to determine if there may be long-term adverse health effects in such persons from such exposure. The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to such dioxins or other dioxins.

(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

(ii) In the event that the Director has not approved such protocol during the one hundred and eighty days following the date of the enactment of this Act, the Director shall (I) submit to the appropriate committees of the Congress a report describing the reasons why the Director has not given such approval, and (II) submit

an update report on such initial report each sixty days thereafter until such protocol is approved.

(C) The Director shall submit to the appropriate committees of the Congress, at each of the times specified in the second sentence of this subparagraph, a report on the Director's monitoring of the conduct of such study pursuant to subparagraph (A)(ii). A report under the preceding sentence shall be submitted before the end of the six-month period beginning on the date of the approval of such protocol by the Director, before the end of the twelve-month period beginning on such date, and annually thereafter until such study is completed or terminated.

(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

(b)(1) Not later than twelve months after the date of the enactment of this Act, the Administrator shall submit to the appropriate committees of the Congress a report on the literature review and analysis conducted under subsection (a)(1).

(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations as the Administrator considers appropriate in light of such results.

(c) For the purpose of assuring that any study carried out by the Federal Government with respect to the adverse health effects in humans of exposure to dioxins is scientifically valid and is conducted with efficiency and objectivity, the President shall assure that—

(1) the study conducted pursuant to subsection (a) is fully coordinated with studies which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to the adverse health effects in humans of exposure to dioxins; and

(2) all appropriate coordination and consultation is accomplished between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of the study carried out pursuant to subsection (a), in the design, conduct, monitoring, or evaluation of such dioxin-exposure studies.

(d) There are authorized to be appropriated such sums as may be necessary for the conduct of the study required by subsection (a).

Approved December 20, 1979.

Pub. L. 97-72, § 401, Nov. 3, 1981, 95 Stat. 1061:

TITLE IV—MISCELLANEOUS PROVISIONS

EXPANSION OF SCOPE OF AGENT ORANGE STUDY

SEC. 401. (a)(1) Paragraph (1) of section 307(a) of the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151; 93 Stat. 1097) is amended to read as follows:

"(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such study, the Administrator may expand the scope of the study to include an evaluation of any long-term adverse health effects in humans of such service as such health effects may result from other factors involved in such service, including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. The Administrator may also include in the study an evaluation of the means of detecting and treating adverse health effects found through the study.

"(B) The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such review and analysis, the Ad-

ministrator may expand the scope of such review and analysis to include a review and analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from other factors involved in service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict or in other comparable situations involving one or more of the factors described in the second sentence of subparagraph (A). The Administrator may also include a review and analysis of the means of detecting and treating adverse health effects found through any study covered by either such review and analysis.".

(2) Paragraph (3) of such section is amended by inserting "first" after "submission of the".

(b) Section 307(b) of such Act is amended—

(1) by inserting "for administrative or legislative action, or both," in paragraph (2) after "recommendations"; and

(2) by adding at the end the following new paragraphs:

"(3) Not later than ninety days after the submission of each report under paragraph (2), the Administrator shall, based on the results described in such report and the comments and recommendations thereon and any other available pertinent information, publish in the Federal Register, for public review and comments, a description of actions, if any, that the Administrator proposes to take with respect to programs administered by the Veterans' Administration. Each such description shall include a justification or rationale for any such action the Administrator proposes to take.

("(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority

to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code, should be extended beyond the expiration period specified by section 610(e)(3) of such title.".

Pub. L. 97-72, § 102, Nov. 3, 1981, 95 Stat. 1047:

VETERANS' HEALTH CARE, TRAINING, AND SMALL BUSINESS LOAN ACT OF 1981

MEDICAL CARE FOR DISABILITIES THAT MAY BE RELATED TO EXPOSURE TO AGENT ORANGE, CERTAIN OTHER HAZARDOUS SUBSTANCES, OR NUCLEAR RADIATION

SEC. 102. (a) Section 610 is amended—

(1) in subsection (a)—

(A) by striking out "and" at the end of the clause (4);

(B) by redesignating clause (5) as clause (6); and

(C) by inserting after clause (4) the following new clause (5):

"(5) a veteran who meets the conditions of subsection (e) of this section; and"; and

(2) by adding at the end the following new subsection:

"(e)(1)(A) Subject to paragraphs (2) and (3) of this subsection, a veteran—

"(i) who served on active duty in the Republic of Vietnam during the Vietnam era, and

"(ii) who the Administrator finds may have been exposed during such service to dioxin or was exposed during such service to a toxic substance found in a herbicide or defoliant used in connection with military purposes during such era,

may be furnished hospital care or nursing home care under subsection (a)(5) of this section for any disability, notwithstanding that there is insufficient medical evidence

to conclude that such disability may be associated with such exposure.

"(B) Subject to paragraphs (2) and (3) of this subsection, a veteran who the Administrator finds was exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with such veteran's participation in the test of such a device or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on September 11, 1945, and ending on July 1, 1946, may be furnished hospital care or nursing home care under subsection (a)(5) of this section for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

"(2) Hospital and nursing home care may not be provided under subsection (a)(5) of this section with respect to a disability that is found, in accordance with guidelines issued by the Chief Medical Director, to have resulted from a cause other than an exposure described in subparagraph (A) or (B) of paragraph (1) of this subsection.

"(3) Hospital and nursing home care and medical services may not be provided under or by virtue of subsection (a)(5) of this section after the end of the one-year period beginning on the date the Administrator submits to the appropriate committees of Congress the first report required by section 307(b)(2) of the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151; 93 Stat. 1098).".

(b) Clause (4) of section 612(i) is amended to read as follows:

> "(4) To any veteran (A) who is a former prisoner of war, or (B) who is eligible for care under section 610(a)(5) of this title.".

Pub. L. 98-160, § 601, Nov. 21, 1983, 97 Stat. 1006:

TITLE VI—RADIATION EXPOSURE STUDY AND GUIDE

RADIATION EXPOSURE STUDY AND GUIDE

SEC. 601. (a)(1)(A) Subject to subparagraphs (B) and (C), the Administrator of Veterans' Affairs, through contracts or agreements with private or public agencies or persons and in consultation with the Director of the Office of Technology Assessment, shall provide for the conduct of epidemiological study of the long-term adverse health effects of exposure to ionizing radiation from the detonation of nuclear devices in connection with the test of such devices or in connection with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on September 11, 1945, and ending on July 1, 1946, in persons who, while serving in the Armed Forces of the United States, were exposed to such radiation. Such study shall include, but not necessarily be limited to, a study of identifiable prevalent illnesses, including malignancies, in the persons exposed.

(B) If the Administrator, in consultation with the Director of the Office of Technology Assessment, determines that it is not feasible to conduct scientifically valid study of any or all of the matters required under subparagraph (A) to be studied—

> (i) the Administrator shall promptly submit to the appropriate committees of the Congress notice of that determination and the reasons therefor; and
>
> (ii) the Director, not later than 60 days after such notice is provided, shall submit to such committees a report evaluating and commenting on such determination.

(C) If the Administrator notifies the Congress of a determination or determinations made pursuant to sub-

paragraph (B), the matter or matters required under subparagraph (A) to be studied to which such determination or determinations apply shall not be required to be studied. If the Administrator notifies the Congress of a determination made pursuant to subparagraph (B) that, taken as a whole, study under subparagraph (A) is not scientifically feasible, the requirement in subparagraph (A) that the Administrator provide for the conduct of epidemiological study shall cease to have effect as if repealed by law.

(2) Not later than one year after the date of the enactment of this Act, the Administrator shall submit to the appropriate committees of the Congress a report on the development of a protocol or protocols for study under paragraph (1)(A). With respect to any such protocol under consideration for development, or in the process of development, that has not been completed by the end of such year, the report shall include an estimate of the completion date for such protocol and an estimate of the cost to be incurred in developing such protocol.

(3)(A) The Director of the Office of Technology Assessment shall monitor the development of the protocol or protocols for, and the conduct of, study under paragraph (1)(A) and shall submit to the appropriate committees of the Congress, at each of the times specified in the next sentence, a report on such monitoring. Reports under the preceding sentence shall be submitted within 6 months after the date of the enactment of this Act, within 12 months after such date, within 25 months after such date, and annually thereafter until such study is completed.

(B) If any protocol to which paragraph (2) applies (or any part of such protocol) is not completed by the end of the 12-month period beginning on the date of the enactment of this Act, the Director shall periodically submit to such committees reports on the status of the development of such proocol.

(4) When the Administrator has entered into a contract or agreement with an agency or person for the conduct of a study under paragraph (1)(A), the Administrator and such agency or person shall submit to the appropriate committees of the Congress a joint report containing a copy of the contract and an estimate f the total cost of such study.

(5)(A) Not later than 24 months after the date of the enactment of this Act, and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report on the status of study under paragraph (1)(A). Such report shall contain (i) a description of the progress on and any results obtained under such study, and (ii) such comments, and such recommendations for administrative and legislative action, as the Administrator considers appropriate in light of such progress and results.

(B) The requirement in subparagraph (A) for the submission of annual reports shall expire upon the submission of a report after the completion of study under paragraph (1)(A).

(6) A contract to carry out study under paragraph (1)(A) may not be entered into unless (A) appropriations for payments under the contract have been provided in advance, or (B) the contract provides that the obligation of the United States to make payments under the contract is contingent upon the availability of funds appropriated for the making of such payments.

(7) There are authorized to be appropriated such sums as may be necessary for the conduct of study under subsection (a)(1)(A).

(b) Not later than one year after the date of the enactment of this Act, the Administrator shall develop and distribute to appropriate Veterans' Administration personnel an indexed reference guide, derived from existing pertinent research-result compilations, designed to

provide Veterans' Administration personnel who either furnish health care or adjudicate claims for benefits under title 38, United States Code, with readily usable information regarding the state of medical and other scientific information on any long-term adverse health effects in humans of exposure to ionizing radiation, including nuclear-device exposure, medical exposure, and occupational exposure.

(c)(1) For the purpose of ensuring that any study, research, or other activity carried out by the Federal Government with respect to adverse health effects in humans from exposure to ionizing radiation is scientifically valid and is conducted with efficiency and objectivity, the President shall ensure that—

(A) activities of the Veterans' Administration in connection with (i) study under subsection (a)(1)(A), (ii) the development of the guide required by subsection (b), and (iii) such additional research as may be identified, as a result of such study or the development of such guide or otherwise, as necessary for the resolution of questions regarding such effects are fully coordinated with studies and other activities which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to such effects, including the radioepidemiological tables mandated by section 7 of the Orphan Drug Act (Public Law 97-414; 96 Stat. 2059); and

(B) appropriate coordination and consultation occurs between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of study under subsection (a)(1)(A), in the design, conduct, monitoring, or evaluation of such radiation-exposure studies or related activities.

(2) Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate committees of the Congress a report containing a description of the steps taken and plans made to ensure the coordination and consultation required by paragraph (1).

Pub. L. 98-542, § 8, Oct. 24, 1984, 98 Stat. 2731:

AMENDMENTS TO REGULATIONS

SEC. 8. (a) Paragraph (3) of section 307(b) of the Veterans' Health Programs Extension and Improvement Act of 1979 (38 U.S.C. 219 note) is amended to read as follows:

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such action. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.".

(b) Paragraph (5) of section 601(a) of the Veterans' Health Care Amendments of 1983 (Public Law 98-160; 97 Stat. 1007) is amended by redesignating subparagraph (B) as subparagraph (C) and inserting after subparagraph (A) the following new subparagraph (B):

"(B) Immediately after the submission of each report under subparagraph (A), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, for the resolution of claims for service connection based on the exposure

specified in subsection (a)(1)(B) of such section. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.".

INTERIM BENEFITS FOR DISABILITY OR DEATH IN CERTAIN CASES

SEC. 9. (a)(1) In the case of a veteran—

(A) who served in the active military, naval, or air service in the Republic of Vietnam during the Vietnam era; and

(B) who has a disease described in subsection (b) that became manifest within one year after the date of the veteran's most recent departure from the Republic of Vietnam during that service,

the Administrator shall (except as provided in subsection (c)) pay a monthly disability benefit to the veteran in accordance with this section.

(2) If a veteran described in paragraph (1) dies from the disease, the Administrator shall pay a monthly death benefit to the survivors of the veteran in accordance with this section.

(b) The diseases referred to in subsection (a) are chloracne and porphyria cutanea tarda.

(c) Benefits may not be paid under this section with respect to a disease occurring in a veteran—

(1) where there is affirmative evidence that the disease was not incurred by the veteran during service in the Republic of Vietnam during the Vietnam era;

(2) where there is affirmative evidence to establish that an intercurrent injury or disease which is a

recognized cause of the disease was suffered by the veteran between the date of the veteran's most recent departure from the Republic of Vietnam during active military, naval, or air service and the onset of the disease; or

(3) if the Administrator determines, based on evidence in the veteran's service records and other records of the Department of Defense, that the veteran was not exposed to dioxin during active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(d)(1) A disability benefit payable to a veteran under this section for a disease described in subsection (b) shall be paid at the rate at which compensation would be payable under chapter 11 of title 38, United States Code, to that veteran for the disability resulting from that disease if the disability were determined to be service-connected.

(2) A death benefit payable under this section to the survivors of a veteran shall be paid to such survivors based upon the eligibility requirements (other than the requirement that death be the result of a service-connected or compensable disability) and at the rates that are applicable to dependency and indemnity compensation under chapter 13 of that title.

(e) A benefit may not be paid under this section with respect to a disease or the death of a veteran for any month for which compensation is payable to that veteran for that disease under chapter 11 of title 38, United States Code, or for which dependency and indemnity compensation is payable for that death under chapter 13 of such title.

(f) A disease establishing eligibility for a disability or death benefit under this section shall be treated for purposes of all other laws of the United States (other than chapters 11 and 13 of title 38, United States Code) as

if such disease were service connected. The receipt of a disability benefit under this section shall be treated for purposes of all other laws of the United States as if such benefit were compensation under chapter 11 of such title, and the receipt of a death benefit under this section shall be treated for purposes of all other laws of the United States as if such benefit were dependency and indemnity compensation under chapter 13 of title 38, United States Code.

(g) For the purposes of this section:

(1) The term "Administrator" means the Administrator of Veterans' Affairs.

(2) The term "Vietnam era" means the period beginning on August 5, 1964, and ending on May 7, 1975.

(3) The term "veteran" has the meaning given that term in paragraph (2) of section 101 of title 38, United States Code, and includes a person who died in the active military, naval, or air service.

(4) The terms "service-connected" and "active military, naval, or air service" have the meanings given those terms in paragraphs (16) and (24), respectively, of section 101 of title 38, United States Code.

Pub. L. 98-542, §§ 2, 5, Oct. 24, 1984, 98 Stat. 2727:

VETERANS' DIOXIN AND RADIATION EXPOSURE COMPENSATION STANDARDS ACT

FINDINGS

SEC. 2. The Congress makes the following findings:

(1) Veterans who served in the Republic of Vietnam during the Vietnam era and veterans who participated in atmospheric nuclear tests or the American occupation of Hiroshima or Nagasaki, Japan, are deeply concerned about possible long-term health effects of exposure to herbicides containing dioxin or to ionizing radiation.

(2) There is scientific and medical uncertainty regarding such long-term adverse health effects.

(3) In section 102 of Public Law 97-22, the Congress responded to that uncertainty by authorizing priority medical care at Veterans' Administration facilities for any disability of a veteran who may have been so exposed (even though there is insufficient medical evidence linking such disability with such exposure) unless the disability is found to have resulted from a cause other than the exposure.

(4) The Congress has further responded to that medical and scientific uncertainty by requiring, in section 307 of Public Law 96-151 and section 601 of Public Law 98-160, the conduct of thorough epidemiological studies of the health effects experienced by veterans in connection with exposure both to herbicides containing dioxin and (if not determined to be scientifically infeasible) to radiation, and by requiring in Public Law 97-414, the developing of radioepidemiological tables setting forth the probabilities of causation between various cancers and exposure to radiation.

REQUIREMENT FOR AND CONTENT OF REGULATIONS

SEC. 5.(a) In carrying out the responsibilities of the Administrator of Veterans' Affairs under section 354 (a)(2) of title 38, United States Code, and in order to promote consistency in claims processing and decisions, the Administrator shall prescribe regulations to—

(1) establish guidelines and (where appropriate) standards and criteria for the resolution of claims for benefits under laws administered by the Veterans' Administration where the criteria for eligibility for a benefit include a requirement that a death or disability be service connected and the claim of service connection is based on a veteran's exposure during service—

(A) in the Republic of Vietnam during the Vietnam era to a herbicide containing dioxin, or

(B) in connection with such veteran's participation in atmospheric nuclear tests or with the American occupation of Hiroshima or Nagasaki, Japan, prior to July 1, 1946, to ionizing radiation from the detonation of a nuclear device; and

(2) ensure that, with respect to those claims, the policy of the United States described in section 2(13) is carried out.

(b)(1)(A) The guidelines required to be established in regulations prescribed under this section shall include guidelines governing the evaluation of the findings of scientific studies relating to the possible increased risk of adverse health effects of exposure to herbicides containing dioxin or of exposure to ionizing radiation. Those guidelines shall require that, in the evaluation of those studies, the Administrator shall take into account whether the results are statistically significant, are capable of replication, and withstand peer review.

(B) The evaluations described in subparagraph (A) shall be made by the Administrator of Veterans' Affairs after receiving the advice of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards (established under section 6). Those evaluations shall be published in the notice section of the Federal Register.

(C) The standards and criteria required to be established in regulations prescribed under this section shall include provisions governing the use in the adjudication of individual claims of the Administrator's evaluations made under subparagraph (B).

(2)(A)(i) In prescribing regulations under this section, the Administrator (after receiving the advice of the Advisory Committee and of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards regarding the diseases described in subparagraph (B)) shall make determinations, based on sound medical and scientific evidence, with respect to each disease described in subparagraph (B) as to whether service connection shall, subject to division (ii) of this subparagraph, be granted in the adjudication of individual cases. In making determinations regarding such diseases, the Administrator shall give due regard to the need to maintain the policy of the United States with respect to the resolution of contested issues as set forth in section 2(13). The Administrator shall set forth in such regulations such determinations, with any specification (relating to exposure or other relevant matter) of limitations on the circumstances under which service connection shall be granted, and shall implement such determinations in accordance with such regulations.

(ii) If the Administrator makes a determination, pursuant to this subparagraph, that service connection shall be granted in the case of a disease described in subparagraph (B), the Administrator shall specify in such regu-

lations that, in the adjudication of individual cases, service connection shall not be granted where there is sufficient affirmative evidence to the contrary or evidence to establish that an intercurrent injury or disease which is a recognized cause of the described disease has been suffered between the date of separation from service and the onset of such disease or that the disability is due to the veteran's own willful misconduct.

(iii) With regard to each disease described in subparagraph (B), the Administrator shall include in the regulations prescribed under this section provisions specifying the factors to be considered in adjudicating issues relating to whether or not service connection should be granted in individual cases and the circumstances governing the granting of service connection for such disease.

(B) The diseases referred to in subparagraph (A) are those specified in section 2(5) and any other disease with respect to which the Administrator finds (after receiving and considering the advice of the appropriate panel of the Scientific Council established under section 6(d)(2)) that there is sound scientific or medical evidence indicating—

(i) a connection to exposure to a herbicide containing dioxin, in the case of a veteran who was exposed to that herbicide during such veteran's service in the Republic of Vietnam during the Vietnam era, or

(ii) a connection to exposure to ionizing radiation, in the case of a veteran who was exposed to ionizing radiation in connection with such veteran's participation in an atmospheric nuclear test or with the American occupation of Hiroshima or Nagasaki, Japan, before July 1, 1946.

(3) The regulations prescribed under this section shall include—

(A) specification of the maximum period of time after exposure to such herbicide or ionizing radiation for the development of those diseases; and

(B) a requirement that a claimant filing a claim based upon a veteran's exposure to a herbicide containing dioxin or to ionizing radiation from the detonation of a nuclear device may not be required to produce evidence substantiating the veteran's exposure during active military, naval, or air service if the information in the veteran's service records and other records of the Department of Defense is not inconsistent with the claim that the veteran was present where and when the claimed exposure occurred.

(c)(1) The Administrator of Veterans' Affairs shall develop the regulations required by this section (and any amendment to those regulations) through a public review and comment process in accordance with the provisions of section 553 of title 5, United States Code. That process may include consideration by the Administrator of the recommendations of the Veterans' Advisory Committee on Environmnetal Hazards and the Scientific Council thereof (established under section 6) with respect to the proposed regulations, and that process shall include consideration by the Administrator of the recommendations of the Committee and the Council with respect to the final regulations and proposed and final amendments to such regulations. The period for public review and comment shall be completed not later than ninety days after the proposed regulations or proposed amendments are published in the Federal Register.

(2)(A) Not later than one hundred and eighty days after the date of the enactment of this Act, the Administrator shall develop and publish in the Federal Register a proposed version of the regulations required to be prescribed by this section.

(B) Not later than three hundred days after the date of the enactment of this Act, the Administrator shall publish in the Federal Register the final regulations together with explanations of the bases for the guidelines, standards, and criteria contained therein required to be prescribed by this section.